



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) Art Unit: 1647  
)  
NIELSEN, et al. ) Examiner: DEBERRY, REGINA  
)  
Serial No.: 09/845,716 ) Washington, D.C.  
)  
Filed: May 2, 2001 ) December 2, 2003  
)  
For: USE OF  $\alpha$ -MSH AND EPO FOR ) Docket No.: NIELSEN=3A  
PREVENTING OR TREATING )  
ISCHEMIC CONDITIONS ) Confirmation No.: 3819

ELECTION WITH TRAVERSE

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S i r :

1. In response to the restriction requirement mailed October 2, Applicants elect group I (claims 1-5, 11-13) with traverse. We are also required to make species restrictions for claims 2, 13, 14 and 15, to the extent that they are included in the elected group.

We see that the original claims were 1-11, and the September 24, 2001 amendment purported to add claims 11-16. These must, of course, be renumbered as 12-17 to avoid duplication. We assume that the Examiner referred to 13-15 as previously numbered, which are now 14-16. Claims "14" and "15" are not within the elected group. Within claim 2, we elect that the organ is "heart". Within claim "13" (now 14) we elect that the condition is "atheromatous disease with thrombosis". Both species elections are made with traverse.

2. The group restriction is traversed on several grounds.

First of all, the Examiner has not clearly demarcated the allegedly distinct inventions. All of the claims relate to a method of treating a condition. The Examiner implies that the groups are differentiated on the basis of "treating different patient populations". However, the Examiner fails to identify which patient population corresponds to each group, or even say how the patient populations are defined. We may conjecture that

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the definition is disease-based, but it is incumbent upon the Examiner to write a clear restriction, not upon us to speculate.

Claims 1 and 2 are in all four groups. Claims 3 and 11 are in group I, II and IV, but not III. Claim 5 is in groups I and II, but not III or IV. The uniquely restricted claims are 4 (I), "12" (now 13) (I), "13" (now 14) (I), "14" (now 15) (II), "15" (now 16) (III) and "16" (now 17) (IV). 4 recites coronary artery disease; "12", stenosis; "14", ischemia secondary to certain conditions; "15", surgery; and "16", septic shock and systemic hypotension.

In order for a restriction to be proper, the Examiner must establish that the claims are directed to distinct inventions. See 35 USC §121, 37 CFR 1.141-1.142, and MPEP 802.01. The Examiner has failed to analyze the claims in the light of the criteria for distinctness.

The fact that claims 1 and 2 are assigned by the Examiner to all four groups implies that what we have here is at worst a "genus-species" situation per MPEP §806.04(a), i.e., the group restriction should be withdrawn, and the Examiner could consider making a species restriction calling for election of a "patient population". However, we believe that even a species restriction is uncalled-for.

We turn next to the Examiner's comments concerning "search and consideration of diverse diseases". For restriction to be proper, the Examiner must show both distinctness and serious burden. MPEP 808.02 requires the examiner to show one of the following:

- (A) separate classification
- (B) separate status in the art
- (C) different field of search.

The Examiner has classified all of groups I-IV into class 514, subclass 2. The Examiner has not asserted a separate status in the art. It thus appears that if there is a "serious burden", it is attributable to a "different field of search".

However, the Examiner has not really quantified how

different the field of search would be if groups II-IV were rejoined to group I. Claim 1 contemplates use of both (1) alpha-MSH (or an equivalent), and (2) EPO (or an equivalent) -- the "and/or" in the restriction is not in the claim. If the use of these two agents in tandem is not disclosed or suggested by the art, then the Examiner has no need to address specific diseases in her search.

The Examiner appears ready to search conditions caused by "ischemia of the tissue", per group I claims 3 and "11" (now 12). Claim "14" (now 15) of group II, nominally dependent on claim 1, recites a "condition caused by ischemia" secondary to various conditions. Claim "16" (now 17) of group IV, while nominally dependent on claim 1, recited "where the ischemia is due to septic shock or conditions associated with systemic hypotension". So the additional burden seems mostly associated with claim "15" (now 16) of group III, reciting surgery and transplation. In these days of computerized searching, we do not think it seriously burdensome to search I-IV and instead of I alone.

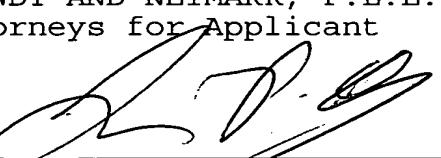
By the preliminary amendment filed on even date herewith, we incorporate the ischemia limitation of claim 3 into claim 1. Thus, the search may now be limited to alpha-MSH & EPO & ischemia.

3. The species restrictions are traversed on the ground that generic claims are allowable.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By:

  
Iver P. Cooper  
Reg. No. 28,005

624 Ninth Street, N.W.  
Washington, D.C. 20001  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:lms  
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